K113244

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Section 5

SYNAPSE MPR Fusion V2.5
510(k) Summary

This Section contains:

510(k) Summary

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FUJIFILM MEDICAL SYSTEMS U.S.A., INC.

FUJIFILM

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SYNAPSE MPR Fusion V2.5

Special 510(k) Summary

Date Prepared: **October 31, 2011**

Submitter's Information

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419 West Avenue
Stamford, Connecticut 06902
Telephone: (203) 602-3774
Facsimile: (203) 363-3813
Contact: Debbie Peacock

Device Name and Classification:

Product Name:	Synapse MPR/Fusion Software V2.5
Classification Name:	Picture Archiving Communication System (PACS)
Classification Panel:	Radiology
CFR Section:	21 CFR 892.2050
Device Class:	Class II
Product Code:	LLZ

Substantial Equivalence/Predicate Devices:

Proposed SYNAPSE MPR/Fusion V2.5 Indications for Use:

Synapse MPR/Fusion software enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, technologists and clinicians. Synapse MPR/Fusion is not intended for Mammography use.

Predicate Mirada XD (K101228) Indications for Use:

Mirada XD is intended to be used by trained medical professionals including, but not limited to, radiologists, nuclear medicine physicians, and physicists.

Mirada XD is a software application intended to display and visualize 2D & 3D multi-modal medical image data. The user may process, render, review, store, print and distribute DICOM 3.0 compliant datasets within the system and/or across computer networks. Supported modalities include, CT, MR, PET SPECT and planar NM. The user may also create, display, print, store and distribute reports resulting from interpretation of the datasets.

Mirada XD allows the user to register combinations of anatomical and functional images and display them with fused and non-fused displays to facilitate the comparison of image data by the user. The result of the registration operation can assist the user in assessing changes in image data, either within or between examinations and aims to help the user obtain a better understanding of the combined information that would otherwise have to be visually compared disjointedly. Mirada XD provides a number of tools such as rulers and region of interests, which are intended to be used for the assessment of regions of an image to support a clinical workflow. Examples of such workflows included, but are not limited to, the evaluation of the presence or absence of lesions, determination of treatment response and follow-up.

Mirada XD allows the user to define, transform and store the export regions of interest structures in DICOM format including RT format for use in radiation therapy planning systems.

Additional Function	*Description*
Additional Modality	Supports Fusion of Nuclear Medicine (SPECT) images.
Save to Synapse Server	Now has the ability to save reformats to new series on Synapse PACS.
Auto correcting orientation	Automatically corrects orientation when scans are performed in supine and prone position.
Fusion combination	Arbitrary combination between CT,MR,PET and NM/SPECT by Drag&Drop on currently-cleared Fusion View (which currently allows for PET CT Fusion only).
Compare in Fusion View	Compare images and measurements in the current study to the previous study in Fusion View.
Provides Additional Functional Enhancements such as:	
• Automatic rotation of PET	Keeping rotating whole MIP image by rolling the mouse wheel while pressing the [Ctrl] key
• Ability to top/bottom	Ability to top/bottom PET and SPECT images using mouse
• Smooth scrolling	Smoother scrolling of whole MIP image in Fusion View
• Reference Line	Draw reference lines in Fusion View.
• Oblique in Fusion View	Rotating plane in Fusion View by dragging a reference line
• Fusion Ratio	Setting default fusion ratio
• Display formats	Additional layout formats are added.
• Top default value in the combo box control in Fusion View	Setting Top default values in the combo box control in Fusion View

Should you have any questions, please contact me by phone at 203-602-3774, fax: 203-3633813 or e-mail at dpeacock@fujifilm.com.

Sincerely,

Debbie Peacock

Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Debbie Peacock
Regulatory Affairs Manager
FUJIFILM Medical Systems USA, Inc.
419 West Avenue
STANFORD CT 06902

DEC 2 2 2011

Re: K113244
Trade/Device Name: Synapse MPR/Fusion software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 12, 2011
Received: December 13, 2011

Dear Ms. Peacock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

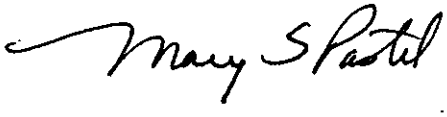
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Synapse MPR/Fusion software**

Indications for Use:

Synapse MPR/Fusion software enables the display, comparison and fusion of 3D (MIP/MPR) of CT, MR, PET and SPECT studies. Typical users are radiologists, technologists and clinicians.

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Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113244